



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Chapter I

[EPA-HQ-OPPT-2021-0599; FRL-8949-01-OCSPP]

TSCA Section 21 Petition for Rulemaking under TSCA Section 6; Reasons for Agency Response; Denial of Requested Rulemaking

AGENCY: Environmental Protection Agency (EPA).

ACTION: Petition; reasons for Agency response.

SUMMARY: This action announces the availability of EPA’s response to a petition received on August 2, 2021, from William D. Bush. The petition requests that EPA determine “that the chemical mixtures contained within cigarettes present an unreasonable risk of injury to health and the environment.” The petitioner also seeks issuance of a rule or order to “eliminate the hazardous chemicals used in a mixture with tobacco,” and to “develop material techniques of biodegradation to counter or reduce” environmental risk from current disposal methods of cigarettes under section 6(a) of the Toxic Substances Control Act (TSCA). After careful consideration, EPA has denied the TSCA section 21 petition for the reasons set forth in this document.

DATES: EPA’s response to this TSCA section 21 petition was signed October 25, 2021.

ADDRESSES: The docket for this TSCA section 21 petition, identified by docket identification (ID) number EPA-HQ-OPPT-2021-0599, is available at <https://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Public Reading Room is by appointment only. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Amy Shuman, Existing Chemicals Risk Management Division (7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-2978; email address: shuman.amy@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of interest to those persons who manufacture (including import), distribute in commerce, process, use, or dispose of cigarettes. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What is EPA's authority for taking this action?

Under TSCA section 21 (15 U.S.C. 2620), any person can petition EPA to initiate a proceeding for the issuance, amendment, or repeal of a rule under TSCA sections 4, 6, or 8, or to issue an order under TSCA sections 4, 5(e), or 5(f). A TSCA section 21 petition must set forth the facts which it is claimed establish that it is necessary to initiate the action requested. EPA is required to grant or deny the petition within 90 days of its filing. If EPA grants the petition, the Agency must promptly commence an appropriate proceeding. If EPA denies the petition, the Agency must publish its reasons for the denial in the *Federal Register*. A petitioner may commence a civil action in a U.S. district court seeking to compel initiation of the requested

proceeding within 60 days of a denial or, if EPA does not issue a decision, within 60 days of the expiration of the 90-day period.

C. What criteria apply to a decision on this TSCA section 21 petition?

1. Legal standard regarding TSCA section 21 petitions.

TSCA section 21(b)(1) requires that the petition “set forth the facts which it is claimed establish that it is necessary” to initiate the proceeding requested. 15 U.S.C. 2620(b)(1). Thus, TSCA section 21 implicitly incorporates the statutory standards that apply to the requested actions. Accordingly, EPA has relied on the standards in TSCA section 21 and in the provisions under which actions have been requested in evaluating this TSCA section 21 petition.

2. Legal standard regarding TSCA section 6(a).

Under TSCA section 6(a), EPA must determine if a chemical substance or mixture in manufacturing, processing, distribution in commerce, use, disposal, or any combination of these activities presents an unreasonable risk of injury to health or the environment. If unreasonable risk to health or the environment is determined, EPA has the authority and obligation to issue a rulemaking placing one or more requirements to the extent necessary so that the chemical substance or mixture no longer presents an unreasonable risk. EPA may eliminate the unreasonable risk of a chemical substance or mixture by regulating manufacture, processing, distribution in commerce, commercial use or disposal of the chemical substance, including by prohibiting, limiting volume, limiting a particular use, restricting concentration, requiring warning and instruction labeling, requiring record-keeping of exposures, notification of end-users, and/or replacement or repurchase by issuance of rulemaking to manufacturers, processors, distributors in commerce, users, and disposers.

3. Legal standard regarding TSCA sections 3(2) and (10).

TSCA section 3(2) excludes from the definition of a “chemical substance” “any mixture,” “tobacco or any tobacco product,” as well as “any food, food additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act [21

U.S.C. 321j) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.” 15 U.S.C. 2602(2). In addition, TSCA section 3(10) defines “mixture” as “any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.”

4. Legal standard regarding TSCA section 26.

TSCA section 26(h) requires EPA, in carrying out TSCA sections 4, 5, and 6, to make science-based decisions using “scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science,” while also taking into account other considerations, including the relevance of information and any uncertainties. 15 U.S.C. 2625(h). TSCA section 26(i) requires that decisions under TSCA sections 4, 5, and 6 be “based on the weight of scientific evidence.” 15 U.S.C. 2625(i). TSCA section 26(k) requires that EPA consider information that is reasonably available in carrying out TSCA sections 4, 5, and 6. 15 U.S.C. 2625(k).

II. Summary of the TSCA Section 21 Petition

A. What action was requested?

On August 2, 2021, EPA received a TSCA section 21 petition (Ref. 1) from William D. Bush (the petitioner) that requests EPA take several actions under TSCA section 6. The petition asks EPA to determine “that the chemical mixtures contained within cigarettes present an unreasonable risk of injury to health and the environment” and seeks the issuance of a rule or order to “eliminate the hazardous chemicals used in a mixture with tobacco; including and not limited to the toxic substance inclusions resulting from tobacco growing or handling techniques,”

and to “develop material techniques of biodegradation to counter or reduce” environmental risk from current disposal methods of cigarettes. The petition also requests “any other prudent methods of toxic mixture substance control [EPA] may see due and fit.”

1. Request for determination that the chemical mixtures contained within cigarettes present an unreasonable risk of injury to health and the environment.

The petition requests that EPA determine that “chemical mixtures contained within cigarettes present an unreasonable risk of injury to health and the environment.” With respect to actions under TSCA section 6, TSCA section 21 provides only for the submission of a petition seeking the initiation of a proceeding for the issuance, amendment, or repeal of a rule under TSCA section 6(a). The purpose of a TSCA section 6 risk evaluation is to determine whether a chemical substance or mixture presents an unreasonable risk to health or the environment under the conditions of use. To initiate a TSCA section 6 risk evaluation, however, the chemical substance or mixture must be designated a high priority for risk evaluation. Prioritization of high priority substances for risk evaluation under TSCA section 6(b) is an activity distinct from rulemaking under TSCA section 6(a). Because TSCA section 21 does not provide an avenue for petitioners to request the initiation of the prioritization process for “chemical mixtures contained within cigarettes,” this Federal Register document does not address this specific request.

2. Request for order by rule that the manufacturing producers of cigarettes eliminate the hazardous chemicals used in a mixture with tobacco.

The petition requests that EPA “[o]rder by [r]ule that the manufacturing producers of cigarettes eliminate the hazardous chemicals used in a mixture with tobacco.” TSCA section 21 provides for the submission of a petition to initiate a proceeding for the issuance, amendment, or repeal of a rule under TSCA sections 4, 6, or 8, or to issue an order under TSCA sections 4, 5(e), or 5(f). As the petitioner is seeking issuance of a rule under TSCA section 6, this Federal Register document addresses this request.

3. Request for order by rule that cigarette manufacturers develop new product designs

that eliminate or reduce the cigarette butt disposal risks to the environment.

The petition asks EPA to “[o]rder by [r]ule that [c]igarette manufacturers develop new product designs which eliminate or reduce the cigarette ‘butt’ disposal risks to the environment.” TSCA section 21 provides for the submission of a petition seeking issuance of a rule under TSCA section 6. However, the requirements listed in TSCA section 6(a) do not allow the Agency to compel a manufacturer to alter existing or develop new product designs. To the extent that the prohibitions and restrictions on manufacturing, processing, or distribution in commerce available in TSCA sections 6(a)(1) and (2) could be interpreted as affecting the design of a product, such issues are described in Unit III.B. To the extent that EPA may apply the TSCA section 6(a)(6) requirement to prohibit or otherwise regulate a manner or method of disposal of a chemical substance, mixture, or article, such a requirement would only apply to a “manufacturer or processor or . . . any other person who uses, or disposes of, it for commercial purposes” and not the unspecified “consumer market disposal methods” cited in the petition. Therefore, this Federal Register document does not address this specific request.

4. Request for other methods of toxic mixture substance control the agency determines to be required.

The petition requests that EPA exercise “any other prudent methods of toxic mixture substance control” that the Agency deems “due and fit.” As a regulatory body, EPA cannot deviate from the statutory remedies established under TSCA section 21. Therefore, a solicitation for EPA to exercise “any other prudent methods” that the Agency deems “due and fit” does not adequately identify an objective that is executable within TSCA section 21. Therefore, this Federal Register document does not address this specific request.

B. What support did the petitioner offer?

To support the request for an order by rule that the manufacturing producers of cigarettes eliminate the hazardous chemicals used in a mixture with tobacco, the petitioner offers information relating to the structure and content of cigarettes, human and environmental health

impacts related to smoking cigarettes, and human and environmental health impacts to discarding cigarette butts (Ref. 1, pp. 2-4). Of 18 points included in that discussion, eight are attributed to an article on the toxicity of cigarette butts and their chemical components for fish (Ref. 2); these points are discussed in detail below. For the remaining ten points, the petitioner does not provide, and EPA could not identify, a reference to support the information presented, which generally applied to the human health and environmental impacts related to smoking cigarettes.

Regarding the eight points attributed to the article on the toxicity of cigarette butts, the petitioner points to estimates of the number of and volume of cigarette butts discarded worldwide (Ref. 1, p. 3, points 9, 10, and 11), as well as the general nature of chemicals in cigarettes and cigarette filters and how such chemicals enter aquatic ecosystems and become “acutely toxic to fish and microorganisms” (Ref. 1, p. 3-4, points 14, 15, and 17). The petitioner also points to the use of “Environmental Protection Agency standard acute fish bioassays” in the analysis of “cigarette butt-derived leachate . . . for aquatic toxicity” and that “[i]n laboratory experimentation, the chemicals that leached from a single cigarette butt (soaked for 24 hours in a liter of water) released enough toxins to kill 50 percent of the saltwater and freshwater fish exposed to it for 96 hours” (Ref. 1, p. 3-4, points 16 and 18).

In addition, the petitioner includes a summary of the findings and policy section of the Pollution Prevention Act (42 U.S.C. 13101) (Ref. 1, pp. 4-5), though TSCA section 21 does not provide an avenue for recourse under such Act. The petitioner states “pollution should be prevented or reduced at the source whenever feasible; pollution that cannot be prevented should be recycled in an environmentally safe manner, whenever feasible; pollution that cannot be prevented or recycled should be treated in an environmentally safe manner whenever feasible; and disposal or other release into the environment should be employed only as a last resort and should be conducted in an environmentally safe manner” and that “source reduction is fundamentally different and more desirable than waste management and pollution control.”

The petitioner also provides two claims: (1) “[t]oxic [c]hemicals added to and included in [c]igarettes are unreasonable;” and (2) “[c]igarette [d]isposal presents a clear unreasonable risk to the [e]nvironment.” (Ref. 1, pp. 5-6). To support the former claim, the petitioner makes general references to, but does not cite or provide for reference *United States v. Philip Morris USA Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006). To support the latter claim, the petitioner states that “research studies of toxic waste entering the environment are clear in identifying cigarette butts as a major hazardous waste emission,” but does not cite or provide any reference to such studies.

III. Disposition of TSCA Section 21 Petition

A. What is EPA’s response?

After careful consideration, EPA has denied this TSCA section 21 petition. A copy of the Agency’s response, which consists of the letter to the petitioner and this document, is posted on the EPA petition website at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-21#cigarettes>. The response, the petition (Ref. 1), and other information is available in the docket for this TSCA section 21 petition. *B. What was EPA’s reason for this response?*

TSCA section 21 does provide for the submission of a petition seeking the initiation of a proceeding for the issuance of a rule under TSCA section 6(a). The petition must “set forth the facts which it is claimed establish that it is necessary to issue” the requested rule. 15 U.S.C. 2620(b)(1). When determining whether the petition meets that burden, EPA will consider whether the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or any combination of such activities, may present an unreasonable risk of injury to health or the environment under TSCA section 6(a). 15 U.S.C. 2605(a).

EPA evaluated the information presented in the petition and considered that information in the context of the applicable authorities and requirements of TSCA sections 6, 21, and 26. Notwithstanding that the burden is on the petitioner to present “the facts which it is claimed establish that it is necessary” for EPA to initiate the rule or issue the order sought, EPA

nonetheless also considered relevant information that was reasonably available to the Agency during the 90-day petition review period. As detailed further in this Unit, EPA finds that the petitioner has not met its burden as defined in TSCA sections 6(a) and 21(b)(1) because the petitioner because cigarettes are not a product that can be regulated under TSCA section 6(a). These deficiencies, among other findings, are detailed in this document.

As previously discussed, TSCA section 6(a) authorizes EPA to determine if a chemical substance or mixture in manufacturing, processing, distribution in commerce, use, disposal, or any combination of these activities presents an unreasonable risk of injury to health or the environment. If unreasonable risk to health or the environment is determined, then EPA must, by rule, issue regulations apply one or more of the following requirements to the extent necessary to that the chemical substance no longer presents such risk. However, TSCA section 3(2)(B), which defines “chemical substance,” excludes “tobacco or any tobacco product.” According to section 201(rr) of the Federal Food, Drug, and Cosmetic Act (FFDCA), “tobacco product” means “any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product.” 21 U.S.C. 321(rr)(1). Section 900(3) of the FFDCA establishes that a “cigarette” is “a product that . . . is a tobacco product . . . and . . . includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco,” and section 901(b) of the FFDCA makes clear that FDA has authority over “all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.” 21 U.S.C. 387(3) and 387a(b). Finally, cigarette butts are not considered as a separate item from a cigarette or tobacco product. (See, e.g., FFDCA sections 904(a)(1) (“the tobacco, paper, filter, or other part of each tobacco product”) and 907(a)(1)(A) (“a cigarette or any of its component parts (including the . . . filter, or paper)”). 21 U.S.C. 387d(a)(1) and 387g(a)(1)(A). EPA thus determined that a “cigarette” is a “tobacco product,” and, therefore, is not a “chemical substance.” Similarly, EPA determined that “tobacco” is not a

“chemical substance.” Therefore, EPA cannot issue a rule pursuant to TSCA section 6(a) to apply requirements to tobacco or cigarettes.

TSCA section 3(2)(B) also excludes “any mixture” from the definition of “chemical substance.” TSCA section 3(10) defines “mixture” generally as “any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction” (emphasis added). Because the petition references “hazardous chemicals used in a mixture with tobacco” and the Agency determined that “tobacco” is not a “chemical substance,” EPA determined that a combination of chemicals with tobacco is not a mixture as defined by TSCA section 3(10). Therefore, EPA cannot issue a rule pursuant to TSCA section 6(a) to apply requirements to “hazardous chemicals used in a mixture with tobacco.”

Additionally, to the extent that the petition referenced the Pollution Prevention Act (42 U.S.C. 13101), the Agency reiterates that TSCA section 21 does not provide an avenue for recourse under such Act.

B. What were EPA’s conclusions?

EPA denied the request to issue of a rule under TSCA section 6(a) because TSCA section 3(2)(B) excludes from the definition of “chemical substance” “any mixture” and “tobacco or any tobacco product.” Because the Agency determined a cigarette (including a cigarette butt) to be a tobacco product, such products are not chemical substances and cannot be subject to a rule issued under TSCA section 6(a). Because EPA also determined that a combination of chemicals with tobacco is not a mixture as defined by TSCA section 3(10), such a combination cannot be subject to a rule issued under TSCA section 6(a).

IV. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket,

even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. Bush, William D. Petition for Issuance of New Rules under Section 15 U.S.C. 2605.

Received August 2, 2021.

2. Slaughter, E., Gersberg, R. M., Watanabe, K., Rudolph, J., Stransky, C., & Novotny, T. E. (2011). Toxicity of cigarette butts, and their chemical components, to marine and freshwater fish. Tobacco control, 20 Suppl 1(Suppl_1), i25–i29.
<https://doi.org/10.1136/tc.2010.040170>.

Authority: 15 U.S.C. 2601 *et seq*.

Dated: October 25, 2021.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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